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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Rudolf Wank

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06/21/2006

BUCHANAN INGERSOLL PC
(INCLUDING BURNS, DOANE, SWECKER & MATHIS)
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EXAMINER

SKELDING, ZACHARY S

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

1. Applicant's Preliminary Amendment to the claims, filed October 20, 2003, has been entered.

Claims 1-13 have been amended.

Claims 1-13 *are pending*.

2. It is noted that claim 1 does not indicate whether the method is to be performed *in vitro* or *in vivo*, however it is apparently an *in vitro* method from the disclosure on pages 4-7 and 14-15 of the instant specification. Thus, for examination purposes claim 1 will be restricted to the extent that it reads on an *in vitro* method for making CAPRI cells.
3. It is noted that claims 5-12 recite administration of CAPRI cells from the method of claim 1, but do not indicate the recipient of the administered cells. For examination purposes claims 5-12 will be restricted to the extent that they reads on administering CAPRI cells to a patient.
4. It is noted that claim 13 reads, "The method according to claim 1, which is undertaken together with medicinal or radiotherapeutic treatment that is matched to the type of disease." For examination purposes claim 13 will be restricted to the extent that it reads on an *in vitro* method of making CAPRI cells AND administering CAPRI cells, undertaken together with medicinal or radiotherapeutic treatment that is matched to the type of disease.
5. It is noted that claim 5 depends on claim 1 and recites "the tumour" however there is no antecedent basis for "the tumour" in either claim 5 or claim 1.

Art Unit: 1644

Species Election

6. This application contain claims directed to the following patentably distinct species of the claimed invention:
7. Applicant is required to elect **one** specific “**stimulation process**” for stimulating CAPRI cells, by indicating any **single** combination of molecules that will be used to stimulate the PBMCs in the **first step** of the stimulation process recited in claim 1, from the group comprising:
 - a. anti-CD3 antibodies,
 - b. immobilized CD3,
 - c. IL-2,
 - d. IL-4, **OR**
 - e. IFN- γ .

AND

Applicant is **further required** to indicate any **single** combination of molecules of a.-e. above which will be present after the addition of naïve PBMC to the cells stimulated in the first step, i.e., in the second step of the “stimulation process”.

These “stimulation process” species are patentably distinct because they employ different combination of molecules which themselves differ in their structures, and/or physiochemical properties, and do not share a common structure that is disclosed to be essential for common utility. Further, examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

Art Unit: 1644

8. Applicant is **also required** to elect whether the claimed method:

(A) does **not** further comprise administration of the CAPRI cells to a patient, **OR**

(B) further comprises administration of CAPRI cells to a patient.

These methods are patentably distinct because they differ with respect to one or more method steps and/or endpoints. Furthermore, the examination of the different method steps and/or endpoints would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

AND

If (B) is selected, applicant is **further required** to elect whether administration of CAPRI cells to a patient:

(A) does **not** further comprise medicinal or radiotherapeutic treatment, **OR**

(B) further comprises medicinal or radiotherapeutic treatment.

These methods are patentably distinct because differ with respect to one or more of ingredients, method steps and/or endpoints. Furthermore, the examination of the different ingredients, method steps and/or endpoints would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and **a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Art Unit: 1644

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.
12. Note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.
13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zachary Skelding, Ph.D.
Patent Examiner
June 17, 2006

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PRIMARY EXAMINER
T31600
6/19/06